

# INTERNATIONAL SEARCH REPORT

Patent Application No

EP 01/082004/004279

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 C12N15/85 C12N15/38 C12N15/36 C12N15/17 C12N15/12 A61K48/00 A61K9/16		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12N A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the International search (name of data base and, where practical, search terms used) EPO-Internal, Sequence Search, BIOSIS, WPI Data, PAJ, EMBASE		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/31137 A (CHIRON CORPORATION; THUDIUM, KENT; SELBY, MARK; ULMER, JEFFREY) 18 April 2002 (2002-04-18)	1,2,7, 10, 12-14, 16,17, 38-49,84
Y	claim 13; examples 1-3	3-6,8,9, 11,15, 18-37
X	WO 02/36792 A (GLAXO GROUP LIMITED; CATCHPOLE, IAN, RICHARD; ELLIS, JONATHAN, HENRY;) 10 May 2002 (2002-05-10)	1,2,7, 12-14, 16,17, 38-49,84
Y	claims 1-4,10; example 4	3-6,8,9, 11,15, 18-37
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *A* document member of the same patent family		
Date of the actual completion of the international search 10 June 2005		Date of mailing of the international search report 12 JUL 2005
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Lonnoy, O

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ROY M J ET AL: "Induction of antigen-specific CD8+ T cells, T helper cells, and protective levels of antibody in humans by particle-mediated administration of a hepatitis B virus DNA vaccine" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 19, no. 7-8, 22 November 2000 (2000-11-22), pages 764-778, XP004225394 ISSN: 0264-410X	3-6,8,9, 11,15, 18-37
A	figure 1	50-83
Y	WO 02/094313 A (POWDERJECT VACCINES, INC; POWDERJECT RESEARCH LIMITED) 28 November 2002 (2002-11-28) figure 1	3-6,8,9, 11,15, 18-37
Y	ZINCKGRAF J W ET AL: "Modulating gene expression using DNA vaccines with different 3'-UTRs influences antibody titer, seroconversion and cytokine profiles" VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 21, no. 15, 2 April 2003 (2003-04-02), pages 1640-1649, XP004413571 ISSN: 0264-410X figure 1	3-6,8,9, 11,15, 18-37
Y	WO 99/03981 A (PPL THERAPEUTICS LIMITED; COLMAN, ALAN; GARNER, IAN; DALRYMPLE, MICHA) 28 January 1999 (1999-01-28) page 12, paragraph 4	4
Y	US 6 110 707 A (NEWGARD ET AL) 29 August 2000 (2000-08-29) column 95, line 66 - column 96, line 12	4
A	ROTONDARO L ET AL: "Efficiency of different viral promoters in directing gene expression in mammalian cells: effect of 3'-untranslated sequences" GENE, ELSEVIER BIOMEDICAL PRESS. AMSTERDAM, NL, vol. 168, no. 2, 12 February 1996 (1996-02-12), pages 195-198, XP004042959 ISSN: 0378-1119	

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/011334 A (GLAXOSMITHKLINE BIOLOGICALS S.A; GLAXO GROUP LIMITED; ERTL, PETER, FRA) 13 February 2003 (2003-02-13) page 62 - page 63 -----	67-83
A	WO 00/23592 A (POWDERJECT VACCINES, INC; FULLER, JAMES, T) 27 April 2000 (2000-04-27) figure 1; example 1 -----	67-83
A	CHAN YU-JIUN ET AL: "Synergistic interactions between overlapping binding sites for the serum response factor and ELK-1 proteins mediate both basal enhancement and phorbol ester responsiveness of primate cytomegalovirus major immediate-early promoters in monocyte and T-lymphocyte cell types" JOURNAL OF VIROLOGY, vol. 70, no. 12, 1996, pages 8590-8605, XP002331463 ISSN: 0022-538X abstract -----	67-83
A	FULLER J T ET AL: "IMMUNE RESPONSES TO HEPATITIS B VIRUS SURFACE AND CORE ANTIGENS IN MICE MONKEYS AND PIGS AFTER ACCELL PARTICLE-MEDIATED DAN IMMUNIZATION" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, NEW YORK ACADEMY OF SCIENCES, NEW YORK, NY, US, vol. 772, 27 November 1995 (1995-11-27), pages 282-284, XP000891484 ISSN: 0077-8923 table 1 -----	50-66
A	WASENAUER G ET AL: "A Cysteine and a Hydrophobic Sequence in the Noncleaved Portion of the Pre-C leader peptide Determine the Biophysical Properties of the Secretory Core Protein (HBe protein) of Human Hepatitis B Virus" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 66, no. 9, September 1992 (1992-09), pages 5338-5346, XP002977293 ISSN: 0022-538X abstract -----	50-66

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national application No.  
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## Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claims 38, 55 and 72, as far as these relate to methods practiced in vivo, and claims 39-43, 49, 56-60, 66, 73-77 and 83 are directed to methods of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-49 and 84 (all totally)

A nucleic acid construct comprising a chimeric promoter sequence and a cloning site for insertion of a coding sequence in operable linkage with the chimeric promoter, wherein the chimeric promoter sequence comprises: (a) a hCMV immediate early promoter sequence; (b) exon 1 and at least a part of exon 2 of the hCMV major immediate early gene; and (c) a heterologous intron provided in place of the intron A region of the hCMV major immediate early gene.

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2. claims: 50-66 (all totally)

A nucleic acid construct comprising (i) a promoter sequence; (ii) a non-translated leader sequence derived from HBV preS2 antigen sequence, HBV e-antigen sequence or HSV type 2 gD antigen sequence; and (iii) a coding sequence operably linked to (i) and (ii) wherein the coding sequence is heterologous to the non-translated leader sequence.

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3. claims: 67-83 (all totally)

A nucleic acid construct comprising: (I) a promoter sequence; (ii) a coding sequence operably linked to the promoter sequence (i); and (iii) an enhancer sequence 3' of and operably linked to the coding sequence (ii); wherein the enhancer sequence (iii) is derived from a 3'UTR of an HBsAg sequence or a 3'UTR of a simian CMV immediate early gene sequence, and the coding sequence (ii) is heterologous to the 3'enhancer sequence.

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WO 0023592	A	27-04-2000	AU 766005 B2	09-10-2003
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